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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,321	11/12/2003	Michael Wandell	36664.00.0013	6492

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EXAMINER	
RAMILLANO, LORE JANET	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,321	WANDELL ET AL.	
	Examiner	Art Unit	
	LORE RAMILLANO	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 20-42* is/are pending in the application.

4a) Of the above claim(s) *22-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,20,21 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/12/08* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's reply filed on 3/12/08 is acknowledged. Claims 1-15 and 20-42 are pending. Claims 22-41 are withdrawn. Claims 4, 6, 8-15, and 20 were amended. Claims 16-19 are cancelled. Claim 42 is a new claim. Claims 1-15, 20-21, and 42 are under examination.

2. This application contains claims 22-41 drawn to an invention nonelected without traverse in the reply filed on 10/3/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

3. The objections to the drawings are withdrawn.

Claim Objections

4. The objection to the claims 4, 6, 8, 11, 17, and 20 are withdrawn.

Claim Rejections - 35 USC § 112

5. The rejection of claims 1-21, under 35 U.S.C. 112, second paragraph, is withdrawn.

Prior art rejections

6. In light of applicant's amendments, the rejection over the prior art is withdrawn. A new rejections follows.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claims 1-15, 20-21, and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Quattrocchi (US 6014438) in view of Fitzgerald et al. ("Fitzgerald," US 6528321).

In figs. 1-4B, Quattrocchi discloses a fluid collector comprising an absorbent substrate and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector. The fluid collector having a first end and a second end, said aperture permitting fluidic access to said first end of said collector, said superstrate having a second aperture relatively proximal said second end of said fluid collector. (i.e. column 5, line 65 to column 8, line 36).

Quattrocchi further discloses a fluid collection device comprising a pair of fluid collectors, and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors. The superstrate comprises a second pair of apertures, each of said fluid collectors having a first end and a second end, said blood receiving openings permitting respectively fluidic access to the first end of one of said fluid collectors, said second pair of apertures each

being respectively relatively proximal said second end of one of said fluid collectors thereby defining a pair of gangs. (i.e. column 5, line 65 to column 8, line 36).

Quattrocchi further discloses a kit comprising the fluid collection device and instructions for using the collection device. The instructions being integral with said device, or the instructions being separate from said device. The kit further comprises a requisition form, said requisition form permitting indication of the type of test to be conducted on the fluid to be collected by the device. The requisition form listing a plurality of test types. The kit further comprises a desiccant comprising silica, said desiccant being present in an amount effective to provide a desiccating protective effect on a blood fluid specimen. The desiccant is contained in a porous pouch. Furthermore, the kit comprises a lancet and a barrier film pouch sized to receive said fluid collection device. The barrier film pouch comprises a laminar structure that includes a polyester film and an aluminum foil film, and at least one self-sealing device. (i.e. column 5, line 65 to column 8, line 36).

Quattrocchi does not specifically disclose a substrate comprising a mat of glass fibers and is coated with xylose and polyvinyl alcohol. Fitzgerald discloses a device 100 comprising a first opposable component 102 and a second opposable component 104. The first opposable component 102 has a sample application zone 106 that contains a matrix of porous material permeable to the liquid portion of blood but capable of trapping the cellular components of blood. The first opposable component 102 also includes a chromatographic medium 108 having a first end 110 and a second end 112. The chromatographic medium 108 includes a detection zone 114, a conjugate zone

116, and optionally a control zone 118. These zones are located on the chromatographic medium 108 so that the conjugate zone 116 is located closer to the first end 110 of the chromatographic medium 108 than is the detection zone 114. The control zone 118, if present, is located furthest from the first end 110 and closest to the second end 112 of the chromatographic medium 108 of the three zones. (i.e. column 15, lines 35-50). Fitzgerald discloses that the matrix can be a woven or non-woven fabric, paper, cellulose, glass fiber, polyester, other polymers, or mixtures of these materials to retain the cellular components of blood (i.e. column 17, lines 44-50). Fitzgerald further discloses that the matrix can alternatively be impregnated with a carbohydrate capable of aggregating blood cells, such as mannitol, sorbitol, inositol, .beta.-D-glucose, .alpha.-D-glucose, D(+)xylose, D(+)mannose, D(-)arabinose, L(+)arabinose, D(+)galactose, L(-)xylose, D-glucoheptose, L-lyxose, lactose, maltose, and sucrose (i.e. column 18, lines 37-50). It would have been obvious to a person of ordinary skill in the art to substitute Quattrocchi's substrate for Fitzgerald's substrate, which comprises glass fibers and is coated with xylose and polyvinyl alcohol because it would be desirable to utilize a matrix comprising glass fibers that is capable of trapping the cellular components of the blood sample to allow the user to easily assay the blood sample. In addition, it would be desirable to incorporate a carbohydrate, such as xylose, to the matrix since it provides a means for aggregating the blood cells in the sample. (i.e. Fitzgerald, column 17, lines 39-50; and column 18, lines 37-40).

Response to Arguments

9. Applicant's arguments filed 3/12/08 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, applicant's argument appears to focus on the teachings of Fitzgerald alone, rather than on the combination of the teachings of Quattrocchi and Fitzgerald. Applicant should note that the test is not whether a suggestion to have an absorbent substrate comprising glass fibers, saccharide, and polyvinyl alcohol (PVA) is found in Fitzgerald alone, but rather what Quattrocchi in view of Fitzgerald would have suggested to one of ordinary skill in the art. Because applicant's arguments do not take into account the combinations of both references, it does not appear that applicant's showing is sufficient to overcome the obviousness rejection.

Furthermore, applicant should note that it is proper to take into account not only specific teachings of the prior art, but also the inferences which one skilled in the art would reasonably be expected to draw from the prior art. Here, Quattrocchi discloses an absorbent substrate. Fitzgerald teaches having a matrix comprising glass fibers and xylose and another matrix having hydrophilic and hydrophobic polymers. The hydrophilic polymer can be PVA. The disclosure of Fitzgerald would infer to one skilled in the art to modify Quattrochi's absorbent substrate to have a substrate comprising

glass fibers, xylose, and PVA because, in addition to the motivation statement indicated in the prior Office action (filed on 12/12/07), Fitzgerald shows it is well known in the art to have combinations of hydrophilic and hydrophobic polymers in an absorbent substrate. In addition, because it is well known in the art that PVA and carbohydrates, such as xylose, tend to be hydrophilic and glass fibers tend to be hydrophobic, one skilled in the art would be motivated to modify Quattrocchi's substrate based on the disclosure of Fitzgerald.

In response to applicant's argument that Fitzgerald's teachings that one of two needed coatings cannot be useful if the other is applied in a subsequent step, examiner does not find this argument convincing. Applicant's argument is not persuasive because the claims at issue are apparatus-type of claims and not product-by-process claims. The patentability of an apparatus-type of claim is based on the structural limitations recited in the claim.

In response to applicant's argument that Quattrocchi does not have an opening to provide access to a fluid collector, examiner disagrees. During examination, the claims may be interpreted as broadly as their terms reasonably allow. Here, it appears that Quattrocchi's specimen sections (58) may be interpreted to be "apertures," because Quattrocchi discloses having an absorbent sample sheet (56), which has small openings to allow the fluid to flow through the sheet. Quattrocchi further discloses in col. 10, lines 33-43, that such specimen sections may be interpreted as apertures because he discloses having the blood sample "fill the specimen section on the card." Furthermore, Quattrocchi discloses having four specimen sections in col. 7, lines 33-52.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano
Examiner
Art Unit 1797